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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,804	11/24/2003	Thomas R. Jenkins	015916-277x	6214
21836	7590	01/09/2006	EXAMINER	
HENRICKS SLAVIN AND HOLMES LLP			PEFFLEY, MICHAEL F	
SUITE 200			ART UNIT	
840 APOLLO STREET			PAPER NUMBER	
EL SEGUNDO, CA 90245			3739	

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/721,804

Applicant(s)

JENKINS ET AL.

Examiner

Michael Peffley

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/6/03  
4/6/04  
8/11/04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Applicant's preliminary amendment of November 24, 2003 canceling claims 11-36 is acknowledged. The following is a complete action on pending claims 1-10.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2 and 7-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Swanson et al (6,076,012).

As shown in Figure 82, Swanson et al disclose a probe comprising an elongate body (424) comprising a catheter having an inflatable coagulation body (col. 35, lines 32+) supported on the elongate body distal region. A control element (440) is associated with the distal end (426) of the elongate body and has a proximal portion extending along the exterior of the elongate body toward the proximal portion (see Figure 82). With regard to applicant's claim 7, each expandable section (i.e. element 430 in Figure 84) is deemed to be a "half-balloon structure". The inflatable body includes micropores (col. 35, lines 32-35) and the structure is heated via electrodes (429).

Claims 1-4 and 7-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Lesh (6,012,457).

As seen in Figure 4, Lesh provides a device comprising an elongate body (130) comprising a catheter having an inflatable tissue coagulation body (160) supported on the elongate body. It is noted that Lesh call the balloon an "ablation element". The examiner maintains that the device is also inherently capable of coagulating tissue as well. A control element (102) has a distal end associated with (i.e. passes through) the distal end of the elongate body via a guidewire aperture (142), and extends along the exterior of the elongate body (see Figure 4). Figure 9D discloses an embodiment where the distal region of the catheter body includes a flexible spline having a hinge portion (i.e. bent portion indicated by element numeral 466). The inflatable structure comprises a "half balloon" structure. That is, a whole balloon inherently includes a half balloon. And the inflatable body may include micropores (col. 21, lines 15-35) and the inflatable body is used to deliver heat to tissue (col. 9, lines 1-10).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (6,076,012).

The Swanson et al device has been addressed above. Swanson et al disclose numerous embodiments. The embodiment depicted in Figures 82-84 (including the inflatable element) does not include the particular flexible spline and hinge element as set forth in applicant's claims 3-6.

The Swanson et al embodiment depicted in Figure 25 discloses an elongate body (184) and a control element (172,174,176) associated with the distal end of the elongate body and extending along an exterior of the elongate body (see Figure 25). The distal region of the elongate body includes a flexible spline (172) that includes a hinge portion (186). This embodiment of the Swanson et al device includes a coagulation body (182) having electrodes (28), but the body is not inflatable like the body shown in Figure 82. The examiner maintains that it would have been obvious to have provided the inflatable body from Figure 82 on the embodiment shown in Figure 25 to provide an alternative treatment device. The Figure 25 embodiment also includes the coagulation body proximal to the hinge element, and the electrodes (28) are used to treat and/or sense tissue (col. 7, lines 45-50).

Again, to have provided the Swanson et al inflatable treatment mechanism on the Figure 25 embodiment to allow for the infusion of fluid during treatment would have been an obvious modification for one of ordinary skill in the art.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Langberg et al (6,527,769) and Pomeranz et al (5,895,417) disclose alternative devices. Lafontaine (6,666,858) discloses a cryo-balloon device

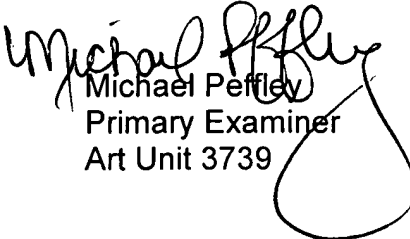
Art Unit: 3739

with a steering tether connected to the distal end, and Tu et al disclose a balloon catheter device with a guidewire connected to the distal end of the catheter and extending along the exterior of the catheter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Michael Peffley  
Primary Examiner  
Art Unit 3739

mp  
January 5, 2006